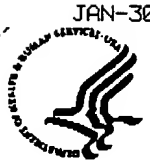

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Reminyl
Docket No.: 01E-0364

JAN 29 2002

The Honorable Q. Todd Dickinson
Director of U.S. Patent and Trademark Office
Commissioner for Patents
Box Pat. Ext.
Washington, D.C. 20231

Dear Director Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,663,318, filed by Janssen Research Foundation, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Reminyl, the human drug product claimed by the patent.

The total length of the regulatory review period for Reminyl is 1,608 days. Of this time, 1,089 days occurred during the testing phase and 519 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 6, 1996.

   The applicant claims October 4, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 6, 1996, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: September 29, 1999.

   FDA has verified the applicant's claim that the new drug application (NDA) for Reminyl (NDA 21-169) was initially submitted on September 29, 1999.

3. The date the application was approved: February 28, 2001.

   FDA has verified the applicant's claim that NDA 21-169 was approved on February 28, 2001.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: John Richards, Esq.
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